



CEDARS-SINAI MEDICAL CENTER.

**AUTHORIZATION FOR USE
AND DISCLOSURE OF
IDENTIFIABLE HEALTH INFORMATION (RESEARCH)**

Use and Disclosure of Health Information

This Authorization is being completed in connection with the Consent Form for Research relating to the Treatment of pituitary Cushing disease with a selective CDK inhibitor, R-roscovitine research study described in the Consent Form. The principal investigator for the research study is Shlomo Melmed, MD (“Principal Investigator”). The sponsor of the research study is National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK) (the “Study Sponsor”). You are being asked for your authorization to allow the research team acting under the direction of the Principal Investigator as described in the Consent Form to review your medical records and collect health information about you (“private information”) from the following sources:

- laboratory tests [such as blood tests and tests to measure liver and kidney function]
- other tests [urine pregnancy test]
- x-rays or scans [electrocardiogram]
- doctor/clinic records
- hospital/medical records
- pathology reports
- mental health records

The following private information about you will be placed in the research study records:

- Name;
- Street address [city, county, precinct, zip code, and their equivalent geocodes];
- Birth date and other indicators of your age;
- Admission date/ discharge date;

- Date of death;
- Telephone numbers;
- Fax numbers;
- Electronic mail address;
- Social Security number [will only be utilized for compensation purposes]
- Medical record numbers;
- Codes assigned in connection with the study to only your information that could be used to identify you.

Who will have access to your private information?

Your private information will be used by and/or shared with the following specific investigators Shlomo Melmed , MD, Ning-Ai Liu, MD PhD, and Vivien Bonert, MD as well as their research team as part of the research study. Reasonable efforts will be made to assure that the research team will have access only to the private information about you that is minimally necessary to conduct the research study. In addition to the research team, various committees of Cedars-Sinai Medical Center, the Sponsor and governmental agencies that oversee research may ask for access to your private information from the research team. These include one or more of the Institutional Review Boards (IRB's) of Cedars-Sinai Medical Center, the Cedars-Sinai Office for Research Compliance, the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services, and other agencies that must receive reports about certain diseases.

Additionally, the following parties may receive information about you:

- Medical and other health care professional students who are assisting with tasks for the research study
- The Study Sponsor (in other words the organization that is paying for the costs of the research study) for matters related to research study oversight, data analysis and use of research results in product development
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

How long will my authorization for use of private information be in effect?

By signing this document, you authorize the use and sharing of your private information until January 1, 2075.

Withdrawal of Authorization

You have the right to withdraw your authorization for us to use your health information at any time. You must write to the principal investigator to withdraw your authorization. The mailing address is: 127 San Vicente Blvd., Suite A6600, Los Angeles, CA 90048. However, if we have provided your information to the sponsor of this research, the study's data coordinating center, or other outside entities, that information cannot be withdrawn. Any information already obtained at the time you withdraw your authorization may continue to be used as necessary to ensure study integrity. For example, it may be necessary to continue to use your information to conduct investigations or to report adverse events.

Further disclosure (sharing) of your private information

Your private information will be shared by the Principal Investigator and Cedars-Sinai Medical Center only as needed for the research study. Cedars-Sinai Medical Center makes an effort to ensure that recipients of your information take steps to maintain the confidentiality of your private information and only receive the information that they need, and not more. Certain individuals or organizations that may receive your private information could though, in very limited circumstances, reveal it for purposes not related to the research study. This would be an unauthorized and illegal disclosure (sharing) of your information. In this study, the Principal Investigator does not anticipate that this will happen. Moreover, in California, the law prohibits such further disclosure of private information without another signed authorization from you (unless the law requires the particular disclosure, such as to report suspected child abuse).

Notice of Rights and Other Information

You may refuse to sign this Authorization. If you refuse to sign this Authorization, you will not be able to participate in the research study. However, standard of care treatment by Cedars-Sinai Medical Center will

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still be made available to you regardless of whether you provide or refuse to sign this Authorization.

You have a right to receive a copy of this Authorization.

The Principal Investigator and Cedars-Sinai Medical Center are required by law to protect your private information. By signing below, you authorize the use or disclosure of your private information in connection with the research study as described above.

SIGNATURE BY THE SUBJECT:

Name of Subject (Print)

Signature of Subject

Date of Signature

SIGNATURE BY THE INVESTIGATOR:

I attest that all the elements of this have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of the Investigator

Date of Signature

SIGNATURE BY THE INTERPRETER/WITNESS

(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter. The witness may be any person who is conversant in both English and the language of the Non-English speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

Signature of Interpreter/Witness

Date of Signature